

Tab 52

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CLIFF STEARNS, FLORIDA
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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

W. J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

April 21, 2003

Mr. Robert Occhifinto
President
NVE Pharmaceuticals
33 Newton Sparta Road
Newton, N.J. 07860

Dear Mr. Occhifinto:

The recent death of 23-year old Baltimore Orioles pitcher Steve Bechler, who reportedly used an ephedra-containing supplement that may have contributed to his untimely death, has raised questions about whether Federal action should be taken to address safety concerns related to ephedra-containing supplements. The Committee on Energy and Commerce, which has jurisdiction over matters relating to food and drugs, has initiated a comprehensive review of safety issues surrounding the use of ephedra-containing supplements. In response to new studies providing additional evidence of safety concerns that may be associated with ephedra-containing supplements, the Department of Health and Human Services (HHS) recently announced several regulatory and enforcement steps intended to protect Americans from potentially serious risks of ephedra-containing supplements. For the first time, HHS issued a public statement cautioning the public about the use of ephedra-containing supplements, particularly in combination with strenuous exercise or other stimulants. Moreover, HHS is seeking expedited public comment on (1) new evidence on health risks associated with ephedra to establish an up-to-date record as quickly as possible to support new restrictions on ephedra-containing products; (2) whether the currently available evidence and medical literature indicate a "significant or unreasonable risk of illness or injury" from dietary supplements containing ephedra; and (3) a new warning label on any ephedra supplements that continue to be marketed.

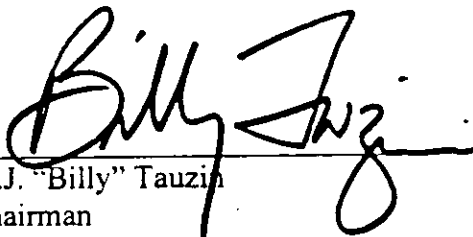
According to various media accounts, ephedra has been linked to reports of numerous deaths and 1,400 reports of health related problems, including strokes, heart attacks and seizures. A recent study published in the Annals of Internal Medicine that compared the safety of ephedra supplements to other herbal supplements concludes that the relative risk for an adverse reaction from ephedra supplements was more than 100-fold higher compared with all other herbs. The study also notes that 64% of all adverse reactions came from supplements containing ephedra, while these products represented only 0.82% of herbal product sales. The recently released results of a RAND Corporation study commissioned by the National Institutes of Health (NIH) provide additional evidence that ephedra-containing supplements may be associated with increased health risks while finding only limited evidence of health benefits resulting from ephedra use.

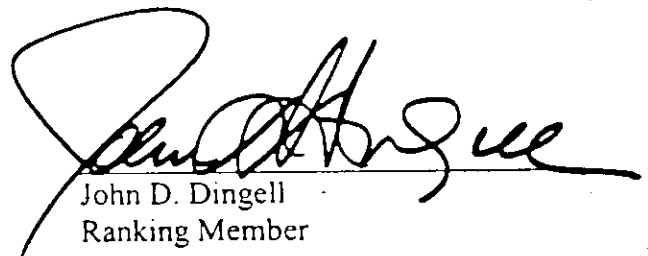
9. From the inception of your company to the present, state the company's overall annual revenue and the amount of revenue per year generated from sales of ephedra-containing products. For each such ephedra-containing product identified in Question 1, provide the total revenue per year, per product.
10. State the reason for your decision to manufacture "ephedra-free" products and whether the decision to develop "ephedra-free" products was the result of concerns about the adverse health-related effects of supplements containing ephedra.
11. All records relating to the development and manufacture of your "ephedra-free" products through the use of ingredients other than ephedra.
12. State whether you manufacture and sell the product known as "Yellow Jackets." If not, provide the date upon which you ceased manufacture and sale of "Yellow Jackets," the reason(s) for your decision to cease manufacturing and/or selling the product, and explain why the product is still available for public consumption on certain websites, such as www.superiorsupplements.com.
13. For each year from 1995 through the present, identify and describe all investigations by state or Federal agencies of your company relating to your products. Include in your response the identity of the investigating agency; the nature of the investigation; and, if applicable, the resolution of the investigation.

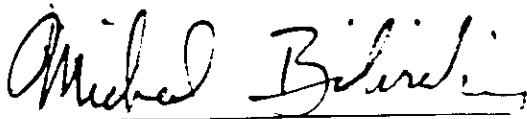
Please note that, for purposes of responding to this request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. The term "you" or "your" means NVE Pharmaceuticals or one or more of its divisions, subsidiaries or affiliates, or related entities.

If you have any questions, please contact Alan Slobodin, Majority Committee Counsel, at (202) 225-2927 or David Nelson, Minority Committee Investigator, at (202) 226-3400.

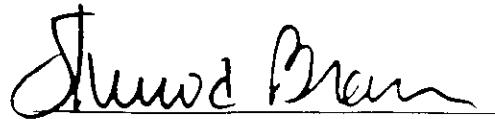
Sincerely,


W.J. "Billy" Tauzin
Chairman

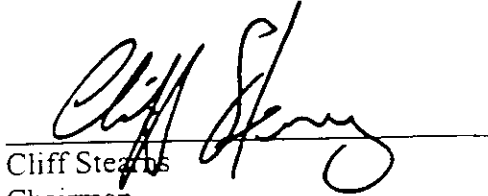

John D. Dingell
Ranking Member



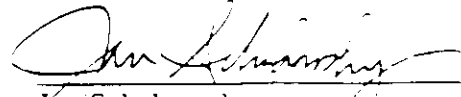
Michael Bilirakis
Chairman
Subcommittee on Health



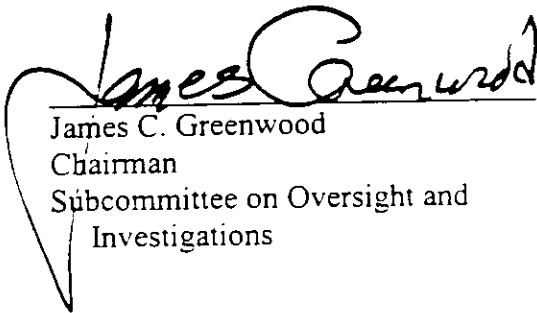
Sherrod Brown
Ranking Member
Subcommittee on Health



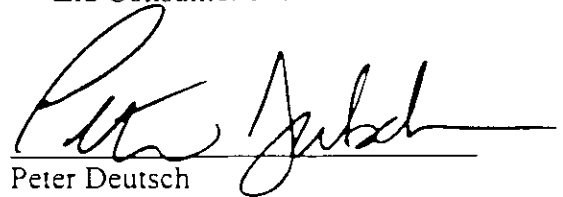
Cliff Stearns
Chairman
Subcommittee on Commerce, Trade,
and Consumer Protection



Jan Schakowsky
Ranking Member
Subcommittee on Commerce, Trade,
and Consumer Protection



James C. Greenwood
Chairman
Subcommittee on Oversight and
Investigations



Peter Deutch
Ranking Member
Subcommittee on Oversight and
Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.